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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,519	05/01/2001	Ralf M. Luche	200125.422	4032

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EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
1652	19

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/847,519</b>	Applicant(s) <b>Luche et al.</b>
Examiner <b>Nashaat T. Nashed</b>	Art Unit <b>1652</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jun 4, 2003

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4)  Claim(s) 3-10 and 12-14 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 3-10 and 12-14 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6)  Other: \_\_\_\_\_

The application has been amended as requested in the communication filed June 4, 2003. Accordingly, claims 1-5, 11, and 15-49 have been canceled and claims 6, 8, 10, and 12 have been amended.

Claims 6-10 and 12-14 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10 and 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth in the prior Office actions, papers numbers 8 and 13.

Claims 6-10 and 12-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In response to the above rejections, Applicants reiterated their previous arguments and argue that the prior Office action has not set forth a *prima facie* case showing that the subject matter of the instant claims, i. e., polynucleotide encoding a Dual Specificity Phosphatase-14 (DSP-14) polypeptide lacks utility.

Applicants' arguments filed 8/6/02 and 6/4/03 have been fully considered but they are not deemed to be persuasive. The examiner disagrees with applicants' arguments. As indicated in the previous Office actions, papers numbers 8 and 13, a *prima facie* case of lack utility has been established, explaining by sound scientific reasoning and support from the art why a person of ordinary skill in the art would doubt that the asserted and specific utility of the amino acid sequence of SEQ ID NO: 2. Applicants have presented no evidence or, indeed, any arguments to establish that the specification established both

a well established and substantial utility. Applicants merely identify several statements in the specification which have been considered by the examiner and assert that "one of ordinary skill in the art would know the uses of DSP-14". Applicants make no effort to explain why they consider the disclosure of some "conserved fragment" is sufficient to establish a specific and substantial utility. Applicants assertions that both U. S. Patent 6,258,582 (582) and 6,132,964 (964) support their asserted utility, and the phospholipase disclosed by Acton in U. S. Patent 6,268,135 (135) has not been demonstrated to have a phospholipase activity are misplaced. The 135 patent is an issued patent and therefore, it is presumed to be valid under 35 U. S. C. § 282. Applicants is reminded that they have not demonstrated any kind of catalytic activity of any kind for the polypeptide of SEQ ID NO: 2 and failed even to demonstrate the protein expresses either *in vivo* or *vitro*. Since the phospholipase utility for the protein in the 135 patent is presumed to be a credible utility and valid, the argument set forth in the prior Office action remains valid. With regard to the 582 and 964, the application identified duel specificity phosphatase as a distinct family of enzymes from those of Ser/Thr-phosphatase and Tyr-phosphatases. Thus, the presence of the homologous domains in other enzymes is not sufficient diagnostic feature for a specific family of enzymes. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action. On page 5, second paragraph, applicant elude to a declaration that will address U. S. patent 6,268,135. There is no declaration accompanied applicants response. Once again, applicant should be reminded with the validity of U. S. patent 6,268,135.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner